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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,379	03/22/2001	Mary Gerritsen	09800081-0026	3936
26263	7590	03/19/2004		
SONNENSCHN NATH & ROSENTHAL LLP P.O. BOX 061080 WACKER DRIVE STATION, SEARS TOWER CHICAGO, IL 60606-1080				
			EXAMINER YAEN, CHRISTOPHER H	
			ART UNIT 1642	PAPER NUMBER

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/815,379	GERRITSEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christopher H Yaen	1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 January 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1,3-5,9,30,31 and 42-54 is/are pending in the application.
- 4a) Of the above claim(s) 5,9,30 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-4,42-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

RE: Gerritsen *et al*

Earliest date of priority: 22 March 2000

1. The amendment filed 1/8/2004 is acknowledged and entered into the record. Accordingly, claims 2,6-8,10-29, and 32-41 are canceled without prejudice or disclaimer, claims 42-54 are newly added.
2. Claims 1,3-5,9,30-31,42-54 are pending, claims 5,9, and 30-31 are withdrawn from further consideration as being drawn to a non-elected subject matter.
3. Claims 1,3-4, and 42-54 are examined on the merits.

#### ***Claim Rejections Maintained - 35 USC § 101***

4. The rejection of claims 1,3-4, and now newly added claims 42-54 under 35 USC 101 and 35 USC 112, 1<sup>st</sup> paragraph as lacking specific and substantial utility is maintained for the reasons of record. Applicant argues that the instantly claimed invention has specific and substantial utility. Applicant further argues that the protein of the instant invention does exist given the sequence is provided in the specification. Moreover, applicant argues that the references cited to show that gene translation is regulated do not provide substantial proof of a protein not existing. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Applicant asserts that the utility of the instant invention is *specific* and *substantial* because the polypeptide of SEQ ID No:4 is associated with a small class of proteins

know to be involved in angiogenesis. Applicant further argues that the experiments that yielded the discovery of SEQ ID No: 4 was done so using experimental models that displayed differential expression of genes associated with angiogenesis, and because of this high expression, the polypeptide of SEQ ID No: 4 could be used as a marker or as a therapeutic agent to inhibit angiogenesis. However, the actual function of the instant protein has not been taught because the instant invention has been based on sequence similarity to a family of proteins known to have function with angiogenesis (see page 52). Although it is possible that the polypeptide of the instant invention is in fact a member of the BAZF family, the actual function of the instant polypeptide has not actually been disclosed. All of the ascribed utilities for the polypeptide of SEQ ID No: 4 are based on the protein function of other BAZF family members, and have not actually been taught to be useful as a marker or as a therapeutic agent. Furthermore, the discovery of the instant invention is based on the differential expression of mRNA and therefore, the use of the protein in terms of a marker for angiogenesis cannot be determined because there are no experiments showing differential expression at the protein level. Further still, there is limited guidance in the art and in the specification as to whether members of the BAZF family or SEQ ID No: 4 would be therapeutically effective for the treatment of angiogenesis, because neither has been shown to be involved in regulating angiogenesis. The use of function blocking antibodies as disclosed by the applicant is not deemed substantial, because the production of antibodies is not deemed specific to the instantly claimed polypeptide and would apply to a broad class of proteins.

Applicant also asserts that the references cited do not in fact show that polypeptides are not translated. Further applicant quotes Alberts et al as stating that the "regulation at the translational level is an exception to the rule" and that increases in gene expression typically correlate with increases in protein translation. However, this is not deemed persuasive because the references are highlighted as examples of mRNA expression as not always indicative of equivalent protein expression. Because one of the claimed utilities of the instant invention is as a marker for angiogenesis, and because the actual expression of the elevated protein has not been determined or disclosed in the instant invention, one of skill in the art has limited guidance in determining whether there is differential expression of the protein so that SEQ ID No: 4 could be used as an angiogenesis marker.

Given the lack of a specific and substantial utility, the rejection under 35 USC 101 is maintained. Furthermore, because the instant invention lacks a specific and substantial utility, one of skill in the art would also be unable to practice the instant invention as claimed. Therefore, the rejection under 35 USC 112, 1<sup>st</sup> paragraph is also maintained.

***Claim Rejections Maintained - 35 USC § 112, 1<sup>st</sup> paragraph***

5. Claims 1,3-4 remain rejected and newly presented claims 42-53 are rejected under 35 USC 112, 1<sup>st</sup> paragraph as lacking proper written description is maintained for the reasons of record. Applicant argues that the specification provides sufficient written description of sequences that are at least 84% identical to that of SEQ ID No: 4, which

would retain hBAZF activity. Applicant further argues that because the sequence of SEQ ID No: 4 is provided in the specification that one of skill in the art would be able to determine variants because methods provided in the specification and available to the skilled artisan would help in the identification of sequences that are at least 84% identical to that of SEQ ID No: 4. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The written description for sequences that are at least 84% identical to that of SEQ ID No: 4 requires more than the base sequence of SEQ ID No: 4. The specification and the claims must provide distinguishing attributes shared by all members of the genus in order to comply with written description. The specification fails to disclose any specific changes made to the base sequence of SEQ ID No.: 4, and therefore the skilled artisan would not know which changes or substitutions are intended in the claimed variants. The highly variant genus claimed does not help in distinguishing the compounds claimed from others in the protein class. As such, one of skill in the art would not be able to recognize that the applicant was in possession of the invention as claimed, because the specification has only described a single sequence, namely SEQ ID No.: 4. Furthermore, the structure or "formula" provided in the specification cannot aid the skilled artisan in distinguishing what is claimed from what is not yet described or disclosed because the specific structure of such sequence has not been taught. The reliance on general knowledge and skill in the art do not supplement the need for specific guidance omitted from the disclosure, because the general teachings of the instant specification cannot provide the skilled artisan with structural

and functional characteristics or attributes that are useful in the identification of the genus claimed. Moreover, the genus claimed has not been supported by a representative number of species so as to be entitled to the broad class of variants claimed, because the genus of sequences claimed is highly variant. Therefore, the specification as written fails to adequately describe the full scope of variants that are at least 84% identical to that of SEQ ID No.: 4.

**All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 1/8/2004.**

### ***Conclusion***

6. No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen  
Art Unit 1642  
March 11, 2004



**GARY NICKOL**  
**PRIMARY EXAMINER**